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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,942	06/02/2000	Daniel Flammang	39558/DBP/E43	6577

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/586,942

Applicant(s)

FLAMMANG, DANIEL

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Comments***

1. The Applicant's comments with respect to the cancelled claims 1-12 and the related newly presented claims 13-25 have been considered. Claims 13-25 have been acted upon in the subsequent paragraphs.

### ***Claim Rejections - 35 USC § 112***

2. Claims 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is unclear. It appears "at least memory" should be --at least one of the memory--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. Claims 13, 14 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by McGee et al. (US 5855592). McGee et al. disclose a system and method for multi-site cardiac defibrillation that monitors electrical events and operates in a local pacing mode. The system/apparatus including an implantable medical device (58), a processing element (62), a sense and analyze module (63), a defibrillation command module (64), a control algorithm (66), one or more arrays (70) comprising flexible strips (67) of memory wire connected at (72) (read as the splitter), and electrodes (68) that are solid rings (c 14, ll 29-53 and c 6, ll 5-11). An outer sheath (44) slides along the catheter tube to enable insertion (c 6, ll 37-42). The spacing between the electrodes in 1 cm (c 9, ll 53-55) and eight electrodes (read as about 5-7 electrically conductive surface portions) are included in each array of the flexible strip (c 9, l 65 – c 10, l 2).

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mc Gee et al. (US 5855592) in view of Cookston et al. (US 5834031). As discussed in paragraph 3 of this action, Mc Gee et al. disclose the claimed invention except for a means to heat the memory member structure to enable the memory member to change shape.

Cookston et al. disclose an apparatus and method for deflecting a tip of a lead or catheter and teaches that it is known to use ohmic heating to enable the user to deform the memory member (c 3, ll 31-39). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method for multi-site cardiac defibrillation as taught by Mc Gee et al., with the ohmic heating of the memory member structure to enable memory member shape change as taught by Cookston et al. to provide a means to enable the user to customize the shape of the leads to the patient so the leads will be properly located to enable optimum cardiac sensing and pacing.

6. Claims 16 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mc Gee et al. (US 5855592) in view of Ljungstrom (EP 0 601 328). As discussed in paragraph 3 of this action, Mc Gee et al. disclose the claimed invention except for the lead configuration containing a septal branch and a lateral branch.

Ljungstrom discloses a defibrillation system and teaches a lead configuration that contains a septal branch and a lateral branch (limb-shaped parts (18) and (19)) with a distal tip electrode to optimize the defibrillation system. The branches as disclosed by Ljungstrom are held in place by an inflatable balloon-like part (20) or movable wire (fig 4 and p 7, l 23 – p 8, l 19), while Mc Gee et al. use memory wire to hold his branches in place. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method for multi-site cardiac defibrillation as taught by Mc Gee et al., with the lead configuration containing a septal branch and a lateral branch as taught by Ljungstrom to provide a large defibrillation surface that is distributed in the heart to avoid damaging the cardiac tissue while optimally defibrillating the heart so flow of blood in the heart is not negatively impacted (p 1, ll 16-16).

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mc Gee et al. (US 5855592) and Ljungstrom (EP 0 601 328) in view of Hess (US 4664120). As discussed in paragraphs 3 and 6 of this action, modified Mc Gee et al. disclose the claimed invention except for the lead configuration including two branches and a ventricular branch with at least one ventricle electrode.

Hess discloses a lead and teaches that it is known to provide a lead configuration that contains two atrial electrode branches (16) and a ventricular branch (15) to provide a multifunctional lead (c 1, ll 8-14). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified system and method for multi-site cardiac defibrillation as taught by Mc Gee et al., with the lead configuration including two branches and a ventricular branch with at least one ventricle electrode as taught by Hess to

provide a lead configuration that provides substantial control, adjustability and feasibility for studies and treatment (c 1, ll 47-52).

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Art Unit: 3762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

JPO  
5/19/02

JEFFREY P. JASTRZAB  
PRIMARY EXAMINER

3762  
5/20/02